

# Process Validation to Improve Food Safety Meat and Poultry

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# ► Validation vs. Verification



# Verification

- ▶ **Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. (NACMCF)**



# Validation

- **“element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, . . . , will effectively control the hazards.  
(NACMCF)**
- **“involves obtaining evidence that control measures, . . . , are capable of controlling the identified hazards.  
(Codex)**



# Comparison of Activities (ICMSF)

## ➤ **Monitoring**

- On-going collection of information on a control measure at the time the control measure is applied.

## ➤ **Verification**

- Determination that the control measures have been appropriately implemented.

## ➤ **Validation**

- Collection and evaluation of scientific, technical and observational information.



# Validation

- ▶ “Validation generally begins with microbiological studies on a laboratory scale, progresses to a pilot plant scale and ends with full validation on a commercial scale when possible or necessary.”
- ▶ Routine sampling plans are not likely to be sufficient for validation studies.



# Regulatory Aspects

- ▶ 9 CFR part 417.4 (1996)
- ▶ USDA-FSIS Directive 6410.1 draft guidance (2010)
- ▶ FSIS Compliance Guideline HACCP Systems Validation (April 2012)
- ▶ HACCP Systems Validation, proposed rule (9 May 2012)
- ▶ “ The Food Safety and Inspection Service (FSIS) is issuing this notice to clarify its requirements for validation . . . .”



# Validation of the Adequacy of HACCP plans

- ▶ Section 417.4 of the meat and poultry regulations requires “Every establishment shall *validate* the HACCP plan’s adequacy in controlling the food safety hazards identified during the hazard analysis....”



# Validation of the Adequacy of HACCP plans

- ▶ adequate validation needs to include both **supporting scientific information as well as in-plant operational data** to "...demonstrate not only that [the establishment's] HACCP plan is theoretically sound, but also that this establishment can implement it and make it work"



# Scientific or Technical Justification

- ▶ A food safety hazard which is reasonably likely to occur must be prevented or controlled
  - ❑ Prevention (pre-requisite programs)
  - ❑ Controlled (CCPs in HACCP Plan)
  
- ▶ Interventions must be validated



# HACCP Systems Validation (proposed Rule)

- 1) the scientific or technical support for the judgments made in designing the HACCP system
- 2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support.



# HACCP Systems Validation

## Scientific and Technical Justification

- 1) the hazard that the measures are intended to address
- 2) the expected level of hazard reduction or prevention that the measures will achieve
- 3) the critical operational parameters that must be met for the measures to be effective
- 4) the processing steps necessary to achieve the specified level of hazard
- 5) how the processing steps can be monitored.



# Scientific or Technical Basis

- The supporting documentation can consist of an article from:
  - Peer-reviewed scientific journal
  - Published processing guidelines
  - Documented challenge study
  - In-house data
  - Regulatory Guidance



# Supporting Documentation

- General Criteria:
- Is the research widely accepted by the relevant professionals?
- Is this the best available scientific data?
- Is it considered dated (more than 5 years old), but still a reliable approach to control?



# FSIS Verification of Validated Interventions—Directive 6410.1

- a) Has the establishment ***considered the level of contamination that may be on the incoming animals?***
- b) Has the establishment ***used that information as a measure to demonstrate that its interventions are capable of addressing the expected contamination load?***



# Scientific or Technical Basis

- ▶ The documentation must identify:
  - Which processing steps will achieve the necessary prevention or reduction
  - Specific *critical* parameters for interventions



# Scientific and Technical Justification

- **Specific control parameters identified**
  - **Pressure (at what point in the wash system)**
  - **Distance of nozzle to carcass surface**
  - **Time (chain speed, seconds/carcass)**
  - **Concentration (how was the concentrate diluted)**
  - **Temperature (at what point? system, nozzle carcass)**



# HACCP Systems Validation Evidence (proposed Rule)

- ▶ **2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support.**



# HACCP Systems Validation Evidence

- ▶ An establishment must develop data to demonstrate that it has and can routinely meet the scientifically documented parameters in its HACCP systems under in-plant conditions, i.e., with its own employees and equipment, and that its **HACCP system, as implemented, is capable of achieving the expected results.**



# HACCP Systems Validation Evidence

- ▶ Data used to support this in-plant demonstration may include in-plant observations, measurements, microbiological test results, documentation to demonstrate that employees have been properly trained regarding the important aspects of their duties, or other information to demonstrate that the establishment can implement the preventive or control measures, as written into the HACCP system, in a manner that achieves the intended food safety objective.



# Microbiological Testing vs. Critical Operating Parameters

- FSIS has revised the draft guidance to **remove the references to the use of in-plant microbiological testing as a necessary part of the in-plant demonstration component** of the HACCP validation process. FSIS has concluded that a key focus of validation should be on the establishment's ability to achieve the scientifically supported critical operating parameters under in-plant conditions.



# And the answer is . . . ?

- ▶ **Regulatory compliance vs. food safety**
- ▶ **Are your interventions working?**
- ▶ **Is your investment in interventions paying off?**



# Would you allow your children...



- ▶ To play soccer on a field that was “99%” clear of land mines?



# Validation Consortium

- I. Presentations at the Reciprocal Meats Conference in Fargo, ND.
- II. Preparing comments on the HACCP Systems Validation Proposed Rule for submission before 9 July.
- III. Preparing a paper for submission Food Protection Trends.
- IV. Hosting an IAFP Workshop on 21 July, prior to the Annual Meeting Providence, RI.